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**DEPARTMENT OF AGRICULTURE**

**Food Safety and Inspection Service**

**9 CFR Parts 352, 354, and 412**

**[Docket No. FSIS-2019-0019]**

**RIN 0583-AD78**

**Prior Label Approval System: Expansion of Generic Label Approval**

**AGENCY:** Food Safety and Inspection Service, USDA.

**ACTION:** Proposed rule.

**SUMMARY:** The Food Safety and Inspection Service (FSIS) is proposing to amend its inspection regulations to expand the circumstances under which FSIS will generically approve the labels of meat, poultry, and egg products. FSIS is also proposing to cease evaluating generically approved labels submitted to FSIS for review.

**DATES:** Submit comments on or before [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

**ADDRESSES:** FSIS invites interested persons to submit comments on this document. Comments may be submitted by one of the following methods:

- *Federal eRulemaking Portal:* This website provides commenters the ability to type short comments directly into the comment field on the web page or to attach a file for lengthier

comments. Go to <http://www.regulations.gov>. Follow the on-line instructions at that site for submitting comments.

- *Mail, including CD-ROMs, etc.:* Send to Docket Clerk, U.S. Department of Agriculture, Food Safety and Inspection Service, 1400 Independence Avenue SW, Mailstop 3758, Room 6065, Washington, DC 20250-3700.

- *Hand or Courier-Delivered Submittals:* Deliver to 1400 Independence Avenue SW, Room 6065, Washington, DC 20250-3700.

*Instructions:* All items submitted by mail or electronic mail must include the Agency name and docket number FSIS-2019-0019. Comments received in response to this docket will be made available for public inspection and posted without change, including any personal information, to <http://www.regulations.gov>.

*Docket:* For access to background documents or comments received, call (202) 720-5627 to schedule a time to visit the FSIS Docket Room at 1400 Independence Avenue SW, Room 6065, Washington, DC 20250-3700.

**FOR FURTHER INFORMATION CONTACT:** Rachel Edelstein, Acting Assistant Administrator, Office of Policy and Program Development, by telephone at (202)720-0399.

**SUPPLEMENTARY INFORMATION:**

**Executive Summary**

To prevent the introduction of adulterated or misbranded products into commerce, the Food Safety and Inspection Service (FSIS) implements a prior approval program for labels intended to be used on federally inspected meat, poultry, and egg products (9 CFR part 412). Without approved labels, these products may not be sold, offered for sale, or otherwise distributed in commerce.

Certain categories of labels or renderings of such labels (sketch labels) must be submitted to FSIS for review and approval before use. However, FSIS considers certain labels that comply with the Agency's labeling rules to be "generically" approved. Such labels are not submitted to FSIS, because they are deemed approved and may be applied to product in commerce.

Generic label approval has been in place in some form since 1983. FSIS has previously expanded the categories of labeling claims eligible for generic approval, most recently in 2013 (78 FR 66826, November 7, 2013). FSIS has also published a proposed rule that, if finalized as proposed, would permit generic approval for egg product labels (83 FR 6314, February 13, 2018). FSIS is now proposing to expand the categories of meat, poultry, and egg product labels that it will deem generically approved and thus not required to be submitted to FSIS. Specifically, under this proposal the following labels would no longer need to be submitted to FSIS for approval: (1) labels on products for

export that deviate from FSIS requirements; (2) labels that list ingredients in the ingredients statement as being certified "organic" (e.g., organic garlic) under the Agricultural Marketing Service (AMS) National Organic Program; (3) labels that display geographic landmarks, such as a foreign country's flag, monument, or map; (4) labels that make "negative" claims identifying the absence of certain ingredients or types of ingredients (e.g., statements such as "No MSG Added," "Preservative Free," "No Milk," "No Pork," or "Made Without Soy"); and (5) labels of products that receive voluntary FSIS inspection (e.g., exotic species under 9 CFR part 352). Finally, FSIS is proposing to cease evaluating labels submitted to FSIS that are eligible for generic approval.

These reforms would result in an estimated 33.8 percent reduction in label submissions (based on fiscal year 2019 data) and reduce Agency costs expended to evaluate the labels (see Table 1). There will not be any negative food safety impacts from this proposal, based on FSIS's experience evaluating these types of labels and the ability of inspection personnel to continue to verify labeling requirements in the field.

There is no cost burden for the industry or FSIS for the proposed rule. This is shown in Table 1 below, which summarizes the costs and benefits of the proposed rule. Industry would experience cost savings of \$468,864, annualized at the 7 percent

discount rate over 10 years, from the reduction in preparing and submitting certain labels for FSIS evaluation. FSIS would experience cost savings of \$235,690, annualized at the 7 percent discount rate over 10 years, from the reduction in label evaluations.

Table 1 - Summary of Annualized Costs and Benefits

	Costs	Cost Savings	Net Benefits
Industry	\$0	\$468,864	\$468,864
Agency	\$0	\$235,690	\$235,690
Total	\$0	\$704,554	\$704,554
Note: Estimates are annualized using a 7 percent discount rate over 10 years.			

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### **I. Background**

The Federal Meat Inspection Act (FMIA) (21 U.S.C. 601 et seq.), Poultry Products Inspection Act (PPIA) (21 U.S.C. 451 et seq.), and Egg Products Inspection Act (EPIA) (21 U.S.C. 1031 et seq.) direct the Secretary of Agriculture to maintain inspection programs designed to ensure that meat, poultry, and egg products are safe, wholesome, not adulterated, and properly marked, labeled, and packaged. These laws prohibit the sale of products under any false or misleading name, marking, or labeling and require the Secretary to approve product marking and labeling (21 U.S.C. 457(c), 607(d), and 1036(b)). The Department's longstanding interpretation of these provisions is that they require the Secretary or his or her representative to approve all labels to be used on federally inspected and passed, domestic and imported, meat, poultry and egg products, before the products may be distributed in commerce.

To implement these provisions, FSIS uses a prior approval program for labels on federally inspected meat, poultry, and egg products (9 CFR part 412). Without approved labels, meat,

poultry, and egg products may not be sold, offered for sale, or otherwise distributed in commerce.

#### **A. Current Label Regulations**

The meat, poultry, and egg products labeling regulations require that meat, poultry, and egg products are truthfully labeled, and that the labeling provides the necessary product information for consumers to make informed purchasing decisions.

There are up to eight features required on meat, poultry, and egg product labels. The required features include: (1) The standardized, common or usual, or descriptive name, of the product (9 CFR 317.2(e), 381.117, and 590.411(c)(1)); (2) an ingredients statement containing the common or usual name of each ingredient of the product listed in descending order of predominance (9 CFR 317.2(f), 381.118, and 590.411(c)(1)); (3) the name and place of business of the manufacturer, packer, or distributor (9 CFR 317.2(g), 381.122, and 590.411(c)(2)); (4) an accurate statement of the net quantity of contents (9 CFR 317.2(h), 381.121, and 590.411(c)(4)); (5) the inspection legend, including the number of the official establishment (9 CFR 312.2(b), 317.2(i), 381.96, 381.123, and 590.411(c)(5)); (6) a handling statement if the product is perishable, e.g., "Keep Frozen" or "Keep Refrigerated" (9 CFR 317.2(k), 381.125(a), and 590.410(a)(1)-(2)); (7) nutrition labeling for applicable meat and poultry products (9 CFR part 317, subpart B; part 381,

subpart Y; and 590.411(e))<sup>1</sup>; and (8) safe handling instructions if the meat or poultry component of the product is not ready-to-eat (9 CFR 317.2(1) and 381.125(b)). In addition, imported meat, poultry, and egg products must bear the country of origin under the product name (9 CFR 327.14(b)(1), 381.205(a), and 590.950(a)(2)).

These required features must appear on the immediate containers of domestic products (9 CFR part 317, subpart A, and part 381, subpart N) and imported products (9 CFR part 327 and part 381, subpart T; 590.411(c); and 590.950(a)). The meat inspection regulations define an "immediate container" as "the receptacle or other covering in which any product is directly contained or wholly or partially enclosed" (9 CFR 301.2). The EPIA and poultry products inspection regulations define an "immediate container" as "any consumer package; or any other container in which poultry products, not consumer packaged, are packed" (21 U.S.C. 1033(d)(1) and 9 CFR 381.1(b)).

The principal display panel, information panel, or other surface of the product label must prominently display the mandatory features. The first six features described above, and the labeling of country of origin for imported products in

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<sup>1</sup> Nutrition labeling for egg products must comply with the provisions of 21 CFR part 101, promulgated under the Federal Food, Drug, and Cosmetic Act and the Fair Packaging and Labeling Act [9 CFR 590.411(e)]



accordance with 9 CFR 327.14 and 381.205, have been required by the meat and poultry inspection regulations for decades. FSIS published regulations that require the nutrition labeling of cooked or heat-treated multi-ingredient meat and poultry products and the display of safe handling instructions in 1993 and 1994, respectively. Given industry's familiarity with these requirements, FSIS typically finds establishments in compliance with its labeling regulations.

The regulations contain other provisions to ensure that no statement, word, picture, design, or device that is false or misleading in any particular, or that conveys any false impression, or that gives any false indication of origin, identity, or quality, appears in any marking or other labeling (9 CFR 317.8, 381.129, and 590.411(f)(1)). Pursuant to the authority contained in section 7(e) of the FMIA (21 U.S.C. 607(e)), section 8(d) of the PPIA (21 U.S.C. 457(d)), and section 7(b) of the EPIA (21 U.S.C. 1036(b)), the Administrator of FSIS may withhold the use of any marking or labeling that is false or misleading, within the meaning of the FMIA, PPIA, and EPIA and their implementing regulations.

## **B. Current Prior Label Approval System**

Under the current regulations, FSIS evaluates sketches of some labels for approval, and approves others generically, i.e., without submission to FSIS for sketch approval. A sketch label

is a printer's proof or other version that clearly shows all required label features, size, location, and indication of final color (9 CFR 412.1(d)). To obtain sketch label approval, domestic meat and poultry establishments, egg product plants, and certified foreign establishments that are eligible to export product to the United States, or their representatives, are required to submit sketch labels to FSIS for evaluation, except when the label is generically approved by the Agency under 9 CFR 412.2.

These firms submit sketch labels accompanied by FSIS Form 7234-1 (11/16/2011), "Application for Approval of Labels, Marking or Device," to the Agency for evaluation. In addition to the required label information, any special claims or statements that the establishment intends to make (e.g., quality claims, animal production raising claims, product origin claims, or nutrient content claims) must be included on the label, along with documentation supporting the claim. The label application must contain the basic information about the establishment and the product, including:

1. Establishment number;
2. Product name;
3. Product formulation;
4. Processing procedures and handling information;
5. Firm name and address;

6. Total available labeling space of the container;
7. Size of the principal display panel; and
8. The Hazard Analysis and Critical Control Point category under which the establishment is producing the meat or poultry product.

FSIS's Labeling and Program Delivery Staff (LPDS), in the Office of Policy and Program Development (OPPD), verifies that sketch labels comply with the applicable requirements. Since July 1, 1996, a final version of a verified sketch label does not have to be submitted to the Agency for evaluation and approval (60 FR 67444, December 29, 1995).<sup>2</sup> All labels are subject to verification for compliance with Agency regulations by FSIS inspectors to ensure that they are accurate, truthful, and not misleading.

### **C. Generic Label Approval**

FSIS allows certain meat, poultry, and egg product labels that bear all required labeling features and that comply with the Agency's labeling regulations to be generically approved (9 CFR 412.2(a)(1)). Generically approved labels do not need to be submitted to FSIS for sketch approval before they can be used on products in commerce. Generic label approval requires that all

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<sup>2</sup> On February 13, 2018 FSIS published the *Egg Products Inspection Regulations* proposed rule (83 FR 6314). If the rule is finalized as proposed, FSIS will also not require submission of final versions of sketch labels for egg products.

mandatory label features are prominent and conform to FSIS regulations. Although such labels are not submitted to FSIS for approval, they are deemed to be approved and, therefore, may be applied to product in accordance with the Agency's prior label approval system.

Generic label approval has been in place in some form since 1983. That year, FSIS promulgated regulations that granted limited label approval authority to Inspectors-In-Charge (IICs) at official establishments and provided generic approval to limited types of labels (e.g., labels for raw, single ingredient meat and poultry products) (48 FR 11410, March 18, 1983). The rulemaking's intent was to reduce the number of labels and other materials submitted for FSIS evaluation and to ease the paperwork burden on official establishments.

Even with the changes made by the rule, the number of labels submitted to the Agency continued to grow. During fiscal year 1991, the Agency processed approximately 167,500 labels. Of these, FSIS approved approximately 87,500 final labels and 60,000 sketch labels. FSIS disapproved approximately 20,000 labels.

On December 29, 1995, FSIS published a final rule that outlined the types of labels and modifications to labels that were deemed to be approved without submission to FSIS, provided that the label displayed all mandatory label features in

conformance with applicable Federal regulations (60 FR 67444). The following labeling was deemed generically approved in that final rule: labels on products with a standard of identity specified in FSIS regulations or *Food Standards and Labeling Policy Book*<sup>3</sup> ("*Policy Book*"); labels for raw, single-ingredient products that do not bear special claims; labels for containers of meat and poultry products sold under contract specifications to the Federal Government; labels for shipping containers that contain fully labeled immediate containers; labels for products not intended for human food (e.g., for the pharmaceutical industry) and for poultry heads and feet to be exported for processing as human food, provided specific regulatory requirements are met; meat and poultry inspection legends that comply with 9 CFR parts 312, 316, and 381, subpart M; labeling on inserts, tags, liners, posters, and like devices that are not misleading and do not reference products; labels for consumer test products not intended for sale; and labels that were previously sketch approved by FSIS and contain no modifications or only certain listed modifications.

The 1995 final rule also transferred responsibility for maintaining labeling records from IICs to official

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<sup>3</sup> Available at: <https://www.fsis.usda.gov/wps/portal/fsis/topics/regulatory-compliance/labeling/Labeling-Policies>.

establishments in the United States and to foreign establishments certified as meeting U.S. requirements under foreign inspection systems. For labels that still required FSIS review, the final rule removed the requirement that firms submit final labels for FSIS approval; thus, today, firms must only submit sketch labels. In the preamble to the 1995 final rule, FSIS stated that it intended to expand generic labeling after it completed an assessment of the modified system (60 FR 67444, 67448).

As explained in the preamble to the 2011 rule, FSIS completed this assessment in 1998 (76 FR 75809, December 5, 2011). FSIS surveyed industry to measure the effects of the generic approval program and sampled 1,513 labels for compliance with Federal regulations and policies. FSIS concluded that the great majority of establishments effectively used generically approved labels and that the gradual implementation of generic label provisions under the 1995 final rule was effective.

In 2011, FSIS published a proposed rule to replace the extensive list of generically approved meat and poultry labeling with a simpler set of label categories required to be submitted for Agency approval. FSIS proposed to require submission of: labels for temporary approval, labels for products produced under religious exemption, labels for export with labeling deviations, and labeling with special statements and claims (76

FR 75809). FSIS also proposed to combine the label approval regulations for meat and poultry products (9 CFR 317.4 and 381.132) into a new part, 9 CFR part 412.

FSIS finalized the 2011 proposed rule on November 7, 2013 (78 FR 66826). The final rule codified the labeling categories and combined the meat and poultry labeling regulations as proposed. However, upon consideration of comments, FSIS finalized the rule with four changes (78 FR 66826, 66827). First, FSIS decided to continue to review generic labels that establishments voluntarily submit for approval; but, the Agency also made clear that such labels would receive lower review priority than non-generic labels. Second, FSIS clarified that special statements or claims (except for "natural" and negative claims) that are defined in FSIS's regulations or in the *Policy Book* are deemed to be generically approved. Third, FSIS determined that a label bearing a child-nutrition (CN) box will not be considered to have a special statement or claim on it that would require sketch approval by FSIS because such information was evaluated for approval by AMS. Finally, the Agency stated that it would no longer add new entries to the *Policy Book*; however, already existing entries may be revised or removed.

In the regulatory text of the 2013 final rule, FSIS stated that it would assess compliance by selecting samples of

generically approved labels from establishments [9 CFR 412.2(a)(2)]. Additionally, after the final rule was published, FSIS received questions about the effectiveness of generic approval. To address these concerns and to establish a protocol for the future national assessment, the FSIS Office of Policy and Program Development (OPPD) conducted a limited assessment of labels.

OPPD conducted this assessment over a three-week period in September 2016.<sup>4</sup> Labeling policy experts traveled to five Federal meat and poultry establishments within the commuting area of FSIS headquarters in Washington DC. Both large and small establishments were visited, including at least one corporation. In each establishment, the labeling policy experts assessed compliance of a representative sample of the generically approved label records on file. At the close of each assessment, the labeling policy experts held a closeout meeting with the FSIS inspection personnel and the establishment management. At this meeting, the labeling policy experts explained any deficiencies, determined if temporary approval was needed for deficient labels, and made recommendations for changes in the establishment's generic label approval and records management

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<sup>4</sup> Methodology available at:  
<https://www.fsis.usda.gov/wps/portal/fsis/topics/regulatory-compliance/labeling/labeling-policies/assessment-generically-approved-label>.



process. An assessment summary letter of this closeout meeting was provided to the establishment, inspection personnel, and the FSIS Office of Field Operations District Manager.

This assessment found a high level of compliance with the requirements. During examination of 270 labels, FSIS identified only three labels with deficiencies necessitating label revocation, and none of these deficiencies involved food safety. During the closing meetings with establishments, inspection and industry personnel determined that more outreach would significantly improve compliance. FSIS has initiated more outreach regarding labeling requirements, as discussed later in this document.

On February 13, 2018], FSIS published the proposed rule, *Egg Products Inspection Regulations* (83 FR 6314). This rule proposed several changes to FSIS's egg product inspection program, one of which adopted by reference FSIS's generic label approval regulation into the egg products regulations (9 CFR 590.412). If the rule is finalized as proposed, egg products will be eligible for generic approval of product labels on the same basis as meat and poultry product labels.

## **II. Proposed Rule**

Since the 2013 rulemaking that established the categories of labels requiring sketch approval, FSIS has gained significant, additional experience evaluating labels required to

be submitted and approved. From that experience, the Agency has concluded that the current label regulations continue to require industry to submit for approval a significant number of labels that could successfully be generically approved. FSIS is therefore proposing changes to its regulations to reduce the number of labels submitted for evaluation by FSIS and to lessen the paperwork burden on official establishments. The reduction in staff time spent approving these labels would allow the Agency to better focus on other consumer protection and food safety activities, such as developing guidance materials, answering labeling policy questions, providing outreach to stakeholders, and ensuring inspection program personnel (IPP) effectively verify that establishments meet labeling requirements. All labels used at official establishments would still be subject to FSIS verification activities in the field. These activities are further described in the section III. "Surveillance and Enforcement" below.

First, FSIS is proposing to extend generic label approval to products only intended for export that deviate from domestic labeling requirements, by removing 9 CFR 412.1(c)(2). FSIS maintains an Export Library that lists requirements for exported products that foreign authorities have officially communicated

to FSIS, including labeling requirements.<sup>5</sup> At times, foreign country labeling requirements conflict with domestic requirements. FSIS regulations (9 CFR 317.7 and 381.128) permit export product labels to deviate from FSIS's domestic labeling requirements in order to comply with foreign country requirements or to be marketed more easily in a foreign country.<sup>6</sup> FSIS IPP verify whether product for export meets requirements listed in the Export Library, including labeling, when certifying products for export. Verification of foreign requirements is ultimately determined by each foreign country's competent authority.

Second, FSIS is proposing to revise the types of "special statements and claims" requiring label submission by providing for generic approval of three additional types of claims. FSIS has observed through its prior label approval system that errors, omissions, and misrepresentations are rare on these types of labels. The proposed changes are to be made by amending 9 CFR 412.1(e) and 412.2(b).

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<sup>5</sup> The Export Library is available at:

<https://www.fsis.usda.gov/wps/portal/fsis/topics/international-affairs/exporting-products/export-library-requirements-by-country>.

<sup>6</sup> Although there is no specific equivalent regulation for egg products, FSIS follows the same policy because such products, intended exclusively for export, must comply with foreign countries' requirements and are therefore not considered misbranded.

The following types of claims would be generically approved:

a. "Organic" claims that appear in a product label's ingredients statement, which designate an ingredient as certified "organic" under AMS's National Organic Program. The ingredients statement on these product labels designates specific ingredients as organic (e.g., organic garlic). FSIS would no longer require the submission and evaluation of supporting documentation to verify that such ingredients are indeed certified as organic by an AMS-recognized third-party certifier. However, FSIS would continue to require that labels certifying a total product as organic to be submitted for FSIS evaluation.

b. "Geographic landmarks" displayed on a product label, such as a foreign country's flag, monument, or map. For example, the following claims displayed on a product label would no longer require sketch approval: a polish flag depicted on a Polish sausage product label, or an outline of the State of Nevada depicted on a product label for beef produced in Nevada.

c. "Negative" claims made on product labels that identify the absence of certain ingredients or types of ingredients. For example, statements such as "No MSG Added," "Preservative Free," "No Milk," "No Pork," or "Made Without Soy," on product labels that do not list these ingredients in the ingredients statement

would no longer have to be evaluated by FSIS before use.

However, FSIS evaluation of labels that bear negative claims relating to the raising of the animal from which the product is derived (e.g., "no antibiotics administered") or negative claims relating to the use of genetically modified ingredients would continue to be required.

Third, FSIS is proposing to permit generic approval of the labels of products that receive voluntary FSIS inspection. FSIS provides several types of voluntary inspection services under the authority of the Agricultural Marketing Act (AMA) (7 U.S.C. 1621 et seq.), including inspection for: rabbits (9 CFR part 354), certain non-amenable species of livestock and poultry animals, such as elk, bison, and migratory water fowl (9 CFR part 352, subpart A, and 9 CFR part 362); and products containing meat or poultry but are not under FSIS jurisdiction, e.g., closed-faced sandwiches (9 CFR 350(c)). At present, labels for some products produced under these voluntary inspection programs are not covered under the Agency's generic approval regulations at 9 CFR 412. FSIS is proposing to permit generic approval for them on the same basis as amenable meat, poultry, and egg products by amending the relevant program regulations

where needed to include references to 9 CFR part 412.<sup>7</sup> For clarity, FSIS will also modify 9 CFR 352.1 to update the section heading and remove unnecessary language.

Finally, FSIS is proposing to cease evaluating generically approved labels submitted voluntarily to LPDS for review. In the 2013 rulemaking that expanded the categories of labels eligible for generic approval, commenters requested to be allowed to continue submitting generic labels for FSIS guidance, evaluation, and approval. FSIS agreed to continue evaluating generic labels that were submitted, giving such labels secondary priority after labels requiring evaluation. Since the 2013 final rule, producers have become more familiar with FSIS's generic labeling requirements, and FSIS has provided additional guidance to assist them in designing compliant labels. Therefore, FSIS's evaluation of otherwise generic labels no longer represents an efficient use of Agency resources.

Comprehensive labeling guidance, including the *FSIS Compliance Guideline for Label Approval*,<sup>8</sup> is available at FSIS's

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<sup>7</sup> The regulations providing for voluntary inspection of non-FSIS-jurisdiction products that contain meat or poultry (9 CFR 350(c)) and products containing non-amenable species of poultry (9 CFR part 362) already adopt 9 CFR part 412 by reference. For this reason, FSIS does not need to make additional regulatory changes to these parts in order to permit generic approval of labels for products receiving these services.

<sup>8</sup> Available at: <https://www.fsis.usda.gov/wps/wcm/connect/bf170761-33e3-4a2d-8f86-940c2698e2c5/Label-Approval-Guide.pdf?MOD=AJPERES>.

website.<sup>9</sup> Information available includes a PowerPoint presentation titled "Labeling 101,"<sup>10</sup> which is used by the Agency as a teaching tool at workshops on meat and poultry label requirements. FSIS also provides guidance on allergen labeling and nutrition labeling,<sup>11</sup> a Label Submission Checklist,<sup>12</sup> a glossary of meat and poultry labeling terms,<sup>13</sup> the *Policy Book*, and questions and answers on various topics, such as generic approval, and the labeling of ingredients.<sup>14</sup>

FSIS will continue to conduct outreach to assist label submitters with labeling compliance in the form of webinars, industry group meetings, training for inspectors, guidance documents published on the FSIS website, and archived public askFSIS questions. Additionally, FSIS provides significant resources to assist label submitters on labels that require FSIS approval prior to use. These include askFSIS, a web portal that allows industry, IPP, and other stakeholders to submit technical

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<sup>9</sup> Available at: <https://www.fsis.usda.gov/wps/portal/fsis/topics/regulatory-compliance/labeling>.

<sup>10</sup> Available at: <https://www.fsis.usda.gov/wps/portal/fsis/topics/regulatory-compliance/labeling/labeling-policies/basics-of-labeling/basics-labeling>.

<sup>11</sup> Available at: <https://www.fsis.usda.gov/wps/portal/fsis/topics/regulatory-compliance/labeling/labeling-policies/nutrition-labeling-policies/nutrition-labeling>.

<sup>12</sup> Available at: <https://www.fsis.usda.gov/wps/portal/fsis/topics/regulatory-compliance/labeling/labeling-procedures/label-submission-checklist>

<sup>13</sup> Available at: <https://www.fsis.usda.gov/wps/portal/fsis/topics/food-safety-education/get-answers/food-safety-fact-sheets/food-labeling/meat-and-poultry-labeling-terms/meat-and-poultry-labeling-terms>.

<sup>14</sup> Available at: <https://www.fsis.usda.gov/wps/wcm/connect/bf170761-33e3-4a2d-8f86-940c2698e2c5/Label-Approval-Guide.pdf?MOD=AJPERES>.

and policy-related questions directly to OPPD.<sup>15</sup> Establishments may also contact FSIS for assistance with labeling questions. FSIS offers resources to assist small and very small plants, including the Small Plant Help Desk, which may be contacted by phone or email and answers questions on FSIS requirements.<sup>16</sup>

In June 2020, the USDA Office of Inspector General (OIG) concluded an audit of FSIS product labeling oversight (OIG audit #24601-0002-23, "Controls Over Meat, Poultry, and Egg Product Labels").<sup>17</sup> In response to the audit recommendations concerning FSIS oversight of generic labeling, the Agency agreed that it would continue to enhance its outreach efforts to ensure establishments are aware of applicable mandatory labeling features for generic labels. FSIS also agreed to update its internal policies to improve IPP label verification activities. Such verification activities are described in section III. "Surveillance and Enforcement" below. FSIS does not believe that the audit's findings or FSIS's responses to the audit affect this proposal.

### **III. Surveillance and Enforcement**

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<sup>15</sup> Available at: <https://askfsis.custhelp.com/>. See also, FSIS Directive 5620.1 Rev. 1, *Using askFSIS*, available at: <https://www.fsis.usda.gov/wps/portal/fsis/topics/regulations/directives>.

<sup>16</sup> The latest information on these resources is available at: <https://www.fsis.usda.gov/wps/portal/fsis/topics/regulatory-compliance/haccp/resources-and-information/svsp-brochure>.

<sup>17</sup> The audit report is available at: <https://www.usda.gov/oig/webdocs/24601-0002-23.pdf>.



Official establishments are required to label meat, poultry, and egg products with labels that are neither false nor misleading and that comply with FSIS's regulations. This is true whether the labels require sketch approval or may be generically approved. Establishments are required to keep records of all labels in accordance with 9 CFR 320.1(b)(10) for meat products, 9 CFR 381.175(b)(6) for poultry products, and 9 CFR 590.200(c) for egg products. These records must include a copy of the final label, the product formulation, processing procedures, and any supporting documentation needed to show that the label complies with the Federal meat, poultry, and egg regulations. Such records must be made available to any duly authorized representative of the Secretary upon request (9 CFR 320.4 and 590.200(b)).

IPP periodically perform a General Labeling Task assigned through FSIS's Public Health Inspection System (PHIS) as part of their regular label verification activities. This task is described in FSIS Directive 7221.1, *Prior Labeling Approval*. It includes verifying that establishments maintain records of the selected labels in accordance with 9 CFR 320.1(b)(10), 381.175(b)(6), and 590.200(c). IPP also verify that final labels applied to product contain all mandatory labeling features and are otherwise in compliance with the applicable regulations by evaluating establishments' labeling records and the labels

themselves (e.g., to verify that the ingredients statement on the label matches the product formula).

IPP document in PHIS any noncompliance found, e.g., if a required labeling feature is missing or if a label requires LPDS evaluation but such evaluation is not documented in the records.<sup>18</sup> Establishments may take corrective action by obtaining label approval through LPDS, bringing the labels into compliance with a pressure sensitive sticker, or by replacing the noncompliant labels with labels that have received prior approval and are in compliance with FSIS's regulations. Final labels that are not in compliance with the regulations may still be granted temporary approval under the conditions listed in 9 CFR 412.1(f). IPP will retain any product bearing a label not in compliance with regulatory requirements as well as those that require, but have not received, LPDS approval. Pursuant to 9 CFR 500.8, FSIS may rescind approval of any false or misleading labels.<sup>19</sup>

FSIS relies on these verification tasks, in addition to evaluation by LPDS, to ensure that meat, poultry, and egg

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<sup>18</sup> If IPP are not performing the General Labeling task but observe a product label that is not in compliance with Federal meat and poultry regulations, they will initiate a directed General Labeling task, retain affected product, and document the noncompliance in PHIS as described above.

<sup>19</sup> If FSIS rescinds or refuses to approve a label, it must explain its reasoning in a written notice, provide an opportunity for the establishment to modify the label, and advise the establishment of its appeal rights (9 CFR 500.8(b)).

product labels are truthful and not misleading. Designating some product labels as generically approved, while maintaining inspection activities for all labels, promotes the effective use of Agency resources. This expansion of generic label approval will not affect consumer protection because FSIS will continue to evaluate labeling that has consumer safety or economic implications, e.g., special statements and claims and requests for temporary approval. For example, FSIS will continue to review labeling that claims product is organic or all natural, makes statements regarding the raising of the animals from which products were derived, displays nutrition factual statements (e.g., 10g protein per serving) on the label, or includes certified claims (e.g., "Certified Gluten Free") on the label.<sup>20</sup>

FSIS invites public comment on these proposed changes and requests data and additional suggestions for ways to make FSIS's generic labeling program more effective and efficient. FSIS considered three alternatives to this proposal: taking no action; the proposed rule, except industry would still have the option to have LPDS evaluate labels that would otherwise be generically approved; and allowing all labels to be generically approved. Although FSIS ultimately decided on the current

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<sup>20</sup> For an extensive list of labeling that requires FSIS approval, see the *FSIS Compliance Guideline for Label Approval*. Available at: <https://www.fsis.usda.gov/wps/wcm/connect/bf170761-33e3-4a2d-8f86-940c2698e2c5/Label-Approval-Guide.pdf?MOD=AJPERES>.

proposal, the Agency will continue to consider the alternatives described below (under the section titled "Alternative Regulatory Approaches") based on the information received.

#### **IV. Executive Orders 12866 and 13563**

Executive Orders (E.O.s) 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). E.O. 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This proposed rule has been designated a "significant" regulatory action under section 3(f) of E.O. 12866. Accordingly, the rule has been reviewed by the Office of Management and Budget under E.O. 12866.

##### *Need for the Rule*

The proposed rule would expand the types of meat, poultry and egg product labels that can be generically approved by FSIS. This would reduce the number of labels evaluated by FSIS and reduce the costs to industry. The labels submitted for FSIS evaluation are becoming more complex and more time-consuming for industry to prepare and for FSIS to evaluate. The proposed rule would improve the efficiency of the label approval system by

expanding generic labeling and making the system more convenient and cost efficient for the industry. This proposed rule also would enhance market efficiency by promoting a faster introduction of new products into the marketplace to meet consumer demand.

#### *Baseline*

Based on FSIS's Label Submission and Approval System (LSAS)<sup>21</sup> data, FSIS evaluated 15,459 unique labels during the 2019 fiscal year (FY). Of these, 5,229 (33.8 percent) would have been generically approved under the proposed rule. This amount (5,229) includes 632 labels currently eligible for generic approval, which firms voluntarily submitted for FSIS review. Many of the 15,459 labels were evaluated by FSIS more than once because they were returned to the producer to primarily make other types of corrections and then resubmitted for FSIS evaluation. FSIS has observed through its prior label approval system that corrections on the types of claims FSIS is proposing to generically approve are rare. In FY 2019, there were 26,158 label adjudications, which included each time a label was evaluated. See Table 2 below for additional details.

Table 2 -- Label Evaluations and Adjudications, FY 2016-2019 (Pre Proposed Rule)

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<sup>21</sup> FSIS's Label Submission and Approval System (LSAS) is a web-based software application that integrates and implements an electronic label application process for establishments to submit label applications to FSIS.

FSIS Labels	2016	2017	2018	2019
Labels FSIS Would Not have Evaluated Under the Proposed Rule	8,534	5,812	6,025	5,229
Total Labels FSIS Evaluated*	22,846	17,958	17,635	15,459
Total Label Adjudications**	30,857	25,125	27,580	26,158

\* This is the total number of labels FSIS evaluated, including the labels that would have been generically approved under the proposed rule.

\*\* Label adjudications include some labels being reevaluated.

FSIS expanded the types of labels and label changes that may be generically approved several times, starting in 1983 when the Agency evaluated 130,000 labels. In 1991, the number of labels evaluated peaked at 167,500. The 1995 final rule (60 FR 67444) amended the prior label approval process by expanding the types of labels and label changes that may be generically approved. From 2003-2010, the number of label adjudication per year averaged 57,457, with a minimum of 43,255 in 2003 and a maximum of 66,061 in 2010. The 2013 final rule (78 FR 66826, November 7, 2013) further expanded generic labeling, decreasing the number of label adjudications to 30,857 in FY 2016 (Table 2). FSIS also proposed to permit generic approval for certain egg product labels in 2018 (83 FR 6314, February, 13, 2018).

The number of FSIS label adjudications decreased after the expansions of generically approved labels. However, the remaining label submissions after each expansion are more time-

consuming for industry to prepare and for FSIS to evaluate. This is because the labels requiring submission after each expansion are generally more complex, with special statements or claims that require FSIS to evaluate a significant amount of supporting documentation.

#### *Expected Costs of the Proposed Rule*

The proposed rule would not impose any new cost on producers that submit labels for FSIS evaluation. Instead, the proposed rule would reduce the regulatory burden on producers that currently submit labels for evaluation and does not change the recordkeeping requirements. Producers already are using generically approved labels and maintaining all labeling records, and thus are experienced in submitting labels for FSIS evaluation.

#### *Expected Benefits of the Proposed Rule*

##### *Industry Impacts*

Industry would realize cost savings from the reduction in FSIS label submissions under the proposed rule. Industry is required to use FSIS Form 7234-1 (OMB control number: 0583-0092) for the initial FSIS label submission. The estimated time to complete this form is 75 minutes per response, which includes reviewing instructions, searching existing data sources, gathering and maintaining the data needed (recordkeeping), and

completing and reviewing the collection of information.<sup>22</sup> FSIS estimates 15 minutes of the 75 minutes are dedicated to recordkeeping. The recordkeeping time is not included in the proposed rule's regulatory impact analysis because the recordkeeping requirements are not changing under the proposed rule; that is, even if the establishment does not need to submit the label to FSIS, the establishment is still required to maintain records to support the label. Therefore, the average industry time to prepare one label submission for FSIS evaluation is 60 minutes (75 minutes - 15 minutes). FSIS also assumed food scientists and technologists would perform this work at a mean hourly wage of \$36.63.<sup>23</sup> A benefits and overhead factor of two<sup>24</sup> was applied to estimate the total labor cost per label submission of \$73.26.

To determine the annual reduction of label submissions, FSIS relied on the average number of labels that FSIS would not have evaluated under the proposed rule from 2016 to 2019, which was 6,400 labels,  $((8,534 + 5,812 + 6,025 + 5,229) / 4)$ , Table

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<sup>22</sup> FSIS Form 7234-1 Application for Approval of Labels, Marking or Device. Last modified 11/16/2011. Available at:

<https://www.fsis.usda.gov/wps/portal/fsis/forms/>

<sup>23</sup> BLS Occupational Employment Statistics, Occupational Employment and Wages, May 2019. 19-1021 Food Scientists and Technologists.

<https://www.bls.gov/news.release/pdf/ocwage.pdf#oes/current/oes191012.htm#nat> > Accessed on 4/30/2020. Last Modified 03/30/2020.

<sup>24</sup> To be consistent with analyses done by the Department of Health and Human Services, this analysis accounts for fringe benefits and overhead by multiplying wages by a factor of 2.



2. Accordingly, FSIS estimates a decrease of 64,000 label evaluations over 10 years under the proposed rule ( $6,400 * 10$ ). As shown in Table 3, FSIS estimates that industry would realize a discounted cost savings of \$3,293,105 (at a 7 percent discount rate) and \$3,999,505 (at a 3 percent discount rate) by FSIS generically approving an additional 64,000 labels over a 10-year period. The cost savings would be \$468,864 when annualized at the 7 and 3 percent discount rate, over 10 years.

Table 3 -- Estimated Industry Cost Savings (2019 dollars)

Total Industry Cost Savings from Reduced Need for FSIS Label Evaluation	Present Value Cost Savings at 7%	Present Value Cost Savings at 3%
Total over 10 years	\$3,293,105	\$3,999,505
Annualized total over 10 years	\$468,864	\$468,864

### *Agency Impacts*

During FY 2019, FSIS employed 14 labeling analysts in LPDS with an average hourly salary of \$64.75 ( $(\$47.52 * 36.25\%) + 47.52 = \$64.75$  for a GS-13 step 1,<sup>25</sup> with an adjusted benefits factor of 36.25 percent).<sup>26</sup> On average, LPDS analysts evaluate labels four hours per day, five days a week, at a cost of

<sup>25</sup> Salary Table 2019-DCB for the locality pay area of Washington-Baltimore-Arlington, DC-MD-VA-WV-PA. Effective January 2019. Available at: [https://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/salary-tables/pdf/2019/DCB\\_h.pdf](https://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/salary-tables/pdf/2019/DCB_h.pdf).

<sup>26</sup> Nussle, Jim. (2008). M-08-13: MEMORANDUM FOR THE HEADS OF EXECUTIVE DEPARTMENTS AND AGENCIES. Executive Office of the President. Available at: <https://www.whitehouse.gov/sites/whitehouse.gov/files/omb/memoranda/2008/m08-13.pdf>.

\$18,130 per week. If the proposed rule is adopted, LPDS analysts would evaluate labels for three hours per day, five days a week, at a cost of \$13,598 per week, because of the reduction in labels submitted to FSIS.

If this proposed rule is adopted, the Agency would realize a discounted cost savings of \$1,655,388 (at a 7 percent discount rate) and \$2,010,484 (at a 3 percent discount rate) for adjudicating fewer labels over a 10-year period. The cost savings would be \$235,690 when annualized at the 7 and 3 percent discount rate over 10 years. See Table 4 for additional details. However, this cost savings from fewer staff hours dedicated towards adjudicating labels would be redirected towards other Agency priority initiatives, such as developing and updating policy and guidance documents, answering questions from askFSIS and other sources, and performing outreach activities. We also anticipate an overall faster label review process from the decline in LPDS label evaluations. This would allow new labels to enter the market faster.

Table 4 -- Estimated Agency Cost Savings (2019 dollars)

Total Agency Cost Savings from Reduced Need for FSIS Label Evaluation	Present Value Cost Savings at 7%	Present Value Cost Savings at 3%
Total over 10 years	\$1,655,388	\$2,010,484
Annualized total over 10 years	\$235,690	\$235,690

#### *Net Benefits*

This proposed rule would be net beneficial because it would reduce the costs to establishments, from submitting fewer labels for FSIS evaluation, while imposing no additional cost burden. The net benefit derived from the proposed rule is estimated to be \$4,948,493 (\$3,293,105 in establishment savings plus \$1,655,388 in Agency savings) discounted at the 7 percent discount rate over a 10-year period. When annualized at the 7 percent discount rate over 10 years, the net cost savings is estimated to be \$704,554. See Table 5 for details.

Table 5 -- Estimated Agency Cost Savings (2019 dollars)

Total Agency and Industry Cost Savings from Reduced Need for FSIS Label Evaluation	Present Value Cost Savings at 7%	Present Value Cost Savings at 3%
Total over 10 years	\$4,948,493	\$6,009,989
Annualized total over 10 years	\$704,554	\$704,554

#### *Alternative Regulatory Approaches*

The Agency considered three alternatives to the proposed rule. The proposed rule was chosen as the least burdensome regulatory approach. The summary of the costs and benefits for the considered alternatives are outlined in Table 6 below.

Table 6 -- Regulatory Alternatives Considered

Alternative	Benefits	Costs	Net Benefit
(1) Take No Action	No Benefit	No potential industry or Agency cost savings.	Net benefits are less than alternative 3.

(2) The Proposed Rule, Except Industry Would Still Have the Option to Have LPDS Evaluate Labels that Would Otherwise be Generically Approved	Industry could benefit from additional FSIS evaluation.	Potential for inefficient use of Agency resources. Industry would also incur costs of submitting the labels and waiting for FSIS evaluation.	Net benefits are less than alternative 3. Although industry could marginally benefit from additional FSIS evaluation, sufficient guidance is available for labels that can be generically approved. Also, industry and the Agency would incur costs from submitting and evaluating such labels.
(3) The Proposed Rule	Potential industry cost savings of \$468,864 and Agency cost savings of \$235,690, annualized at the 7 percent discount rate over 10 years.	No Cost	Net benefits are \$704,554 annualized at the 7 percent discount rate over 10 years.
(4) Allow All FSIS Labels to be Generically Approved	The Agency and industry would benefit from time savings by eliminating FSIS label evaluation.	Costs include potentially increasing the number of misbranded products.	Net benefits are less than alternative 3 as the potential costs of misbranded products from eliminating FSIS label evaluation outweighs the time savings benefit.

#### *Alternative 1 -- No Action (Baseline)*

FSIS considered keeping the current regulations and taking no action. Taking no action would mean that industry and the Agency would not experience costs savings from the reduction of labels submitted for FSIS evaluation under the proposed rule. Industry

would therefore not realize the estimated reduction of 64,000 label submissions over 10 years and would not experience an annualized cost savings of \$468,864 at the 7 percent discount rate over 10 years. The Agency would not experience time savings from the reduction of label evaluations. Therefore, the Agency rejects this alternative.

*Alternative 2 - The Proposed Rule, Except Industry Would Still Have the Option to Have LPDS Evaluate Labels that Would Otherwise be Generically Approved*

FSIS considered an alternative of proposing the same generically approved label categories except FSIS would continue to evaluate those labels that would otherwise be generically approved. Currently, industry can submit labels that can be generically approved for voluntary FSIS evaluation, although this evaluation is not needed prior to entering the market. When industry submits these types of labels for voluntary FSIS evaluation, they are reviewed with a lower priority than other labels, and thus take more time for FSIS to approve. Although industry may marginally benefit from the additional FSIS evaluation, the process is inefficient and raises unnecessary costs. Industry could more quickly get FSIS assistance on these types of labels through other guidance, such as askFSIS.

In addition, FSIS would have to take the time to process and evaluate these labels, when reviewer time could be spent on higher

priorities, such as food safety and policy related issues (e.g., concerning allergens). Industry would also incur costs in preparing and submitting the labels for FSIS evaluation while they could get FSIS help through other outlets without incurring these expenses. For these reasons, FSIS rejects this alternative.

#### *Alternative 3 - The Proposed Rule*

The proposed rule yields cost savings for both the industry and the Agency. There is no additional cost burden from the proposed rule. The potential cost savings for industry is \$468,864, annualized at the 7 percent discount rate over 10 years. This covers the time industry saves from not preparing and submitting the labels for FSIS evaluation.

The potential cost savings for FSIS is \$235,690, annualized at the 7 percent discount rate over 10 years. This covers the time FSIS saves from not evaluating the proposed generically approved labels. Since there is no additional burden for this proposed rule, FSIS determined this to be the preferred alternative.

#### *Alternative 4 - All Labels are Generically Approved*

FSIS also considered an alternative that would allow all labels to be generically approved, requiring no prior approval by FSIS. This alternative may increase the number of misbranded products going into commerce, as LPDS would no longer verify the information on complex labels. An increase in misbranded products that contain incorrect, false, or misleading

information may result in a loss of consumer confidence in information on food labels. There is also cost associated with discarding and reprinting misbranded labels that the industry may suffer. Therefore, FSIS believes the labels that would still require prior evaluation under the proposed rule, such as labels with animal raising or natural claims, benefit from LPDS evaluation due to the complex nature and need for supporting documentation of these claims.

This alternative would yield time savings for industry from no longer preparing and submitting labels for FSIS evaluation. FSIS would also experience time savings from no longer evaluating these labels. However, the potential costs of misbranded products entering commerce, resulting from the elimination of all LPDS label evaluation, would outweigh the benefits of the time savings.

## **V. Regulatory Flexibility Act Assessment**

The FSIS Administrator has made a preliminary determination that this proposed rule would not have a significant economic impact on a substantial number of small entities in the United States, as defined by the Regulatory Flexibility Act (5 U.S.C. 601). This determination was made because small producers would experience costs savings from the reduced number of label submissions for FSIS evaluation.

Based on LSAS and the Public Health Information System (PHIS)<sup>27</sup> data, FSIS estimates 92.3 percent (4,825/5,229) of the label submissions in 2019, which would have been generically approved under the proposed rule, are from small or very small Hazard Analysis and Critical Control Point (HACCP) sized establishments. Under the HACCP size definitions, large establishments have 500 or more employees and small establishments have fewer than 500 but more than 10 employees. Very small establishments have fewer than 10 employees or annual sales of less than \$2.5 million. Small and very small establishments, like large establishments, follow the same standards for generic and sketch approval of labels. Small and very small producers, therefore, would not be disadvantaged because the proposed rule would minimize the regulatory burden on all producers.

Based on 2019 LSAS data, about 12 percent (627/5,229) of labels that would have been generically approved under the proposed rule, were submitted from 19 label consultant firms. These firms are very small, usually having one to four employees. Many of these firms provide a range of services, including label courier services, label consultation and

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<sup>27</sup> PHIS is FSIS's electronic data analytic system, used to collect, consolidate, and analyze data in order to improve public health.



regulatory compliance, or label design. This proposed rule may impact their label courier business. However, the impact on these firms is small as their other business, such as label consultations, would not be affected. Therefore, this proposed rule would not have a significant economic impact on the small label consultant firms.

#### **VI. Executive Order 13771**

Consistent with E.O. 13771 (82 FR 9339, February 3, 2017), FSIS has estimated that this proposed rule would yield cost savings. Assuming a 7 percent discount rate, a perpetual time horizon, and a starting year of 2021, the proposed rule, if finalized, is estimated to yield approximately \$502,337 (2016\$) in annual cost savings. Therefore, if finalized as proposed, this rule would be an E.O. 13771 deregulatory action.

#### **VII. Paperwork Reduction Act**

FSIS has reviewed the paperwork and recordkeeping requirements in this proposed rule in accordance with the Paperwork Reduction Act (44 U.S.C. 3501, et seq.). The Administrator has determined that the proposed rule would not create any additional collection, paperwork, or recordkeeping burdens.

FSIS is proposing to expand the circumstances under which it will generically approve the labels of meat, poultry, and processed egg products. Under this final rule, more official and foreign establishments will be able to use the generic approval of product

labels. As a result, fewer labels will need to be submitted and evaluated by FSIS. The relevant information collection, 0583-0092, Marking, Labeling, and Packaging, will have a net reduction of 6,400 burden hours because of the increased use of generic labeling.

#### **VIII. E-Government Act**

FSIS and USDA are committed to achieving the purposes of the E-Government Act (44 U.S.C. 3601, *et seq.*) by, among other things, promoting the use of the Internet and other information technologies and providing increased opportunities for citizen access to Government information and services, and for other purposes.

#### **IX. Executive Order 12988, Civil Justice Reform**

This proposed rule has been reviewed under Executive Order 12988, Civil Justice Reform. Under this rule: (1) All State and local laws and regulations that are inconsistent with this rule will be preempted; (2) no retroactive effect will be given to this rule; and (3) no administrative proceedings will be required before parties may file suit in court challenging this rule.

#### **X. Executive Order 13175, Consultation and Coordination with Indian Tribal Governments**

This rule has been reviewed in accordance with the requirements of Executive Order 13175, Consultation and

Coordination with Indian Tribal Governments. Executive Order 13175 requires Federal agencies to consult and coordinate with tribes on a government-to-government basis on policies that have tribal implications, including regulations, legislative comments or proposed legislation, and other policy statements or actions that have substantial direct effects on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes or on the distribution of power and responsibilities between the Federal Government and Indian tribes.

The USDA's Office of Tribal Relations (OTR) has assessed the impact of this rule on Indian tribes and determined that this rule does not to our knowledge, have tribal implications that require tribal consultation. If a tribe requests consultation, FSIS will work with the OTR to ensure meaningful consultation is provided where changes, additions, and modifications identified herein are not expressly mandated by Congress.

#### **XI. USDA Non-Discrimination Statement**

In accordance with Federal civil rights law and U.S. Department of Agriculture (USDA) civil rights regulations and policies, the USDA, its Agencies, offices, and employees, and institutions participating in or administering USDA programs are prohibited from discriminating based on race, color, national

origin, religion, sex, gender identity (including gender expression), sexual orientation, disability, age, marital status, family/parental status, income derived from a public assistance program, political beliefs, or reprisal or retaliation for prior civil rights activity, in any program or activity conducted or funded by USDA (not all bases apply to all programs). Remedies and complaint filing deadlines vary by program or incident.

*How to File a Complaint of Discrimination*

To file a complaint of discrimination, complete the USDA Program Discrimination Complaint Form, which may be accessed online at

[http://www.ocio.usda.gov/sites/default/files/docs/2012/Complain\\_combined\\_6\\_8\\_12.pdf](http://www.ocio.usda.gov/sites/default/files/docs/2012/Complain_combined_6_8_12.pdf), or write a letter signed by you or your authorized representative.

Send your completed complaint form or letter to USDA by mail, fax, or email:

*Mail:*

U.S. Department of Agriculture  
Director, Office of Adjudication  
1400 Independence Avenue, SW  
Washington, DC 20250-9410

*Fax:* (202) 690-7442

*E-mail:* [program.intake@usda.gov](mailto:program.intake@usda.gov)

Persons with disabilities who require alternative means for communication (Braille, large print, audiotape, etc.), should contact USDA's TARGET Center at (202) 720-2600 (voice and TDD).

### **XIII. Environmental Impact**

Each USDA agency is required to comply with 7 CFR part 1b of the Departmental regulations, which supplements the National Environmental Policy Act regulations published by the Council on Environmental Quality. Under these regulations, actions of certain USDA agencies and agency units are categorically excluded from the preparation of an Environmental Assessment (EA) or an Environmental Impact Statement (EIS) unless the agency head determines that an action may have a significant environmental effect (7 CFR 1b.4 (b)). FSIS is among the agencies categorically excluded from the preparation of an EA or EIS (7 CFR 1b.4 (b)(6)).

FSIS has determined that this proposed rule, which would refine the Agency's existing label approval program, will not create any extraordinary circumstances that would result in this normally excluded action having a significant individual or cumulative effect on the human environment. Therefore, this action is appropriately subject to the categorical exclusion from the preparation of an environmental assessment or environmental impact statement provided under 7 CFR 1b.4(6) of the U.S. Department of Agriculture regulations.

### **XIII. Congressional Review Act**

Pursuant to the Congressional Review Act at 5 U.S.C. 801 et seq., the Office of Information and Regulatory Affairs has determined that this document is not a "major rule," as defined by 5 U.S.C. 804(2).

### **XIV. Additional Public Notification**

Public awareness of all segments of rulemaking and policy development is important. Consequently, FSIS will announce this **Federal Register** publication on-line through the FSIS Web page located at: <http://www.fsis.usda.gov/federal-register>.

FSIS will also announce and provide a link to it through the FSIS *Constituent Update*, which is used to provide information regarding FSIS policies, procedures, regulations, **Federal Register** notices, FSIS public meetings, and other types of information that could affect or would be of interest to our constituents and stakeholders. The *Constituent Update* is available on the FSIS Web page. Through the Web page, FSIS is able to provide information to a much broader, more diverse audience. In addition, FSIS offers an e-mail subscription service which provides automatic and customized access to selected food safety news and information. This service is available at: <http://www.fsis.usda.gov/subscribe>. Options range from recalls to export information, regulations, directives, and

notices. Customers can add or delete subscriptions themselves and have the option to password protect their accounts.

## **List of Subjects**

### **9 CFR Part 352**

Food labeling, Meat inspection, Reporting and recordkeeping requirements.

### **9 CFR Part 354**

Administrative practice and procedure, Animal diseases, Food labeling, Meat inspection, Rabbits and rabbit products, Reporting and recordkeeping requirements, Signs and symbols.

### **9 CFR Part 412**

Food labeling, Food packaging, Meat and meat products, Meat inspection, Poultry and poultry products, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, FSIS is proposing to amend 9 CFR Chapter III as follows:

## **PART 352 – EXOTIC ANIMALS AND HORSES; VOLUNTARY INSPECTION**

1. The authority citation for part 352 continues to read as follows:

AUTHORITY: 7 U.S.C. 1622, 1624; 7 CFR 2.17(g) and (i), 2.55.

2. In § 352.7:

a. Revise the section heading;

b. Remove from the introductory text the phrase "Wording and form of inspection mark."; and

c. Add a sentence at the end of the introductory text.

The revision and addition read as follows:

**§ 352.7 Marking and labeling of inspected products.**

\* \* \*

All labels intended for use on inspected and passed exotic animal products must be approved in accordance with Part 412 of this chapter.

\* \* \* \* \*

**PART 354 – VOLUNTARY INSPECTION OF RABBITS AND EDIBLE PRODUCTS THEREOF**

3. The authority citation for part 354 continues to read as follows:

AUTHORITY: 7 U.S.C. 1622, 1624; 7 CFR 2.17(g) and (i), 2.55.

4. Revise § 354.60 to read as follows:

**§ 354.60 Approval of official identification.**

All labels intended for use on inspected and passed rabbit products which bear any official identification must be approved in accordance with Part 412 of this chapter.

**PART 412 – LABEL APPROVAL**

5. The authority citation for part 412 continues to read as follows:

AUTHORITY: 21 U.S.C. 451-470, 601-695; 7 CFR 218, 2.53.



6. In § 412.1, remove and reserve paragraph (c)(2) and revise paragraph (e) to read as follows:

**§ 412.1 Label approval.**

\* \* \* \* \*

(e) "Special statements and claims" are statements, claims, logos, trademarks, and other symbols on labels as defined in this paragraph.

(1) The following are considered special statements and claims:

(i) Those not defined in the Federal meat and poultry products inspection regulations or the Food Standards and Labeling Policy Book;

(ii) "Natural" claims, regardless of whether they are defined in the Food Standards and Labeling Policy Book.

(iii) Health claims (including graphic representations of hearts), ingredient and processing method claims (e.g., high-pressure processing), structure-function claims, claims regarding the raising of animals (e.g., "no antibiotics administered"), products labeled as organic (except for those where only individual ingredients are labeled as organic), and instructional or disclaimer statements concerning pathogens (e.g., "for cooking only" or "not tested for E. coli O157:H7").

(2) The following are not considered special statements and claims:

(i) Allergen statements (e.g., "contains soy") applied in accordance with the Food Allergen Labeling and Consumer Protection Act.

(ii) Negative claims regarding ingredients not listed in the ingredients statement (i.e., "No MSG Added," "Preservative Free," "No Milk," "No Pork," or "Made Without Soy").

(iii) Statements that characterize a product's nutrient content in compliance with Title 9 of the CFR, such as "low fat."

(iv) Claims related to geographical significance, such as "German Brand Made in the US," or those that make a country of origin statement on the label of any meat or poultry product "covered commodity," or displays of geographic landmarks, such as a foreign country's flag, monument, or map.

\* \* \* \* \*

7. Revise § 412.2(b) to read as follows:

**§ 412.2 Approval of generic labels.**

\* \* \* \* \*

(b) Generically approved labels are labels that bear all applicable mandatory labeling features (i.e., product name, handling statement, ingredients statement, the name and place of business of the manufacturer, packer or distributor, net weight, legend, safe handling instructions, and nutrition labeling) in accordance with Federal regulations and do not bear special

statements and claims as defined in paragraph 412.1(e) of this part.

Done at Washington, DC.

**Paul Kiecker,**

*Administrator.*

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